months from index date were identified. ADs were categorized as tricyclic antidepressants (TCAs), selective serotonin reuptake inhibitors (SSRIs), and new antidepressants (NADs). The adherence measures of AD therapy include 90-days medication possession ratio (MPR, <75% as nonadherent), persistence (duration of uninterrupted therapy > 90 days with 14-day permissible gap), and switching of AD class within 180-days were used. Relapse was defined as hospitalization or emergency department visit due to depression, suicide attempts, or reinitiation of AD therapy after at least 6 months from previous AD treatment. Cox proportional hazards model was used to estimate risk ratios of relapse with 95% confidence intervals for each adherence measure. **RESULTS:** A total of 88,079 patients satisfied the selection criteria, among which mean age of 45.2 years and 67.3% of women. Overall relapse rate was 29.5%. Adherence (MPR≥75%) or persistence (duration of uninterrupted therapy >90 days) showed non-significant estimates of relapse risk (aRR=0.99[0.97-1.02] and 1.01[0.97-1.04], respectively). Patients who switched AD class within 180 days showed increased risk of relapse (aRR=1.18[1.15-1.21]). **CONCLUSIONS:** Various definitions of adherence led to different estimates of relapse rate. Diverse aspects of adherence should be considered when studying the association between the medication adherence and clinical outcomes.

PMH82

VALIDATION AND PSYCHOMETRIC EVALUATION OF A BRIEF COMBINED ASSESSMENT OF DEPRESSION AND ANXIETY

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OBJECTIVES: The Patient Health Questionnaire-4 (PHQ-4; Kroenke, 2009) is a composite instrument constructed from the GAD-2 and PHQ-2 questionnaire assessments of depression and anxiety symptoms. We sought to build on prior validation of the instrument by evaluating the reproducibility of the PHQ-4 and testing equivalence between paper and electronic administration modes. **METHODS:** The PHQ-4 and other questionnaire measures were administered to a sample of adults recruited through newspaper and web-based advertisements in eight US cities. Participants were randomized to complete the PHQ-4 on either paper or computerized format. A one-week retest was completed at home. Reproducibility and mode equivalence were assessed using the intraclass correlation coefficient (ICC). Cronbach's alpha was calculated to assess internal consistency. To assess convergent validity, the correlation of the PHQ-4 to the Mental Component Subscore (MCS) and the Mental Health Index (MHI-5) of the SF-36 was calculated. T-tests were used to assess the difference in PHQ scores by participants' self-reported prior diagnosis of clinical depression. **RESULTS:** Of the 258 participants that completed baseline assessment, 251 (97%) completed the one-week retest. The mean age of participants was 48.6 years, 61% were female, and 71% were Caucasian. About half (n=130; 50.4%) reported a prior depression diagnosis. The mean PHQ-4 score was 4.0(±3.3), and the ICC between paper and computerized administration was 0.86. The ICC for the one-week retest was 0.88, and the PHQ-4 was found to be internally consistent (Cronbach's alpha=0.90). Significant correlations were found with the MCS ($r=-0.79$; $p<0.001$) and the MHI-5 ($r=-0.86$; $p<0.001$), and the instrument discriminated between participants with and without prior depression diagnoses (mean PHQ-4 scores of 5.8 vs. 2.1, $p<0.001$). **CONCLUSIONS:** The PHQ-4 was observed to have adequate reproducibility and internal consistency; appropriate convergent validity; and significantly discriminates between participants with prior diagnoses of depression. Equivalence between paper and web-based administration was demonstrated.

PMH83

ESTIMATING SAMPLE SIZE FOR PSYCHOMETRIC STUDIES USING CONFIRMATORY FACTOR ANALYSIS

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OBJECTIVES: Sample size determination is critical in planning psychometric studies in order to achieve stable results. Confirmatory factor analysis (CFA) is an essential aspect of content validation and for psychometric studies. The current study reviewed three approaches for CFA-based power analyses: N:q rule-of-thumb (N:q), RMSEA-based sample size (RMSEA-BSS), and Monte Carlo simulation (MC). **METHODS:** N:q states 10 (reliable loadings) or 20 participants (less reliable loadings) are required for every free parameter. RMSEA-BSS uses the sampling distribution of RMSEA to determine the power of a CFA for a predicted level of RMSEA versus a given RMSEA criterion (similar to the power of a t-test for one mean versus another). the MC is used to investigate the performance of statistical estimators under various conditions wherein data are generated for over k>10,000 simulated datasets to understand the sampling distributions of various parameters. MC has many benefits, including statistical estimates of the sample size requirements for a very specific CFA model. These three approaches were examined on the CFA for a common 10-item depression instrument. **RESULTS:** For n:Q, a total of 22 free parameters were present, thereby requiring between 220 or 440 subjects. RMSEA-BSS was calculated using a free website (people.ku.edu/~preacher/rmsea/rmsea.htm), resulting in a sample size estimate of 283 (alpha=0.05, CFA $df=31$, power=0.8, RMSEA criterion=0.06, and RMSEA estimate=0.02). A sample size of 183 was calculated using MC. **CONCLUSIONS:** N:q is simple yet the least accurate technique used. The RMSEA-BSS approach is not as accurate nor as flexible as MC, nor as quick as N:q. It is accessible to most psychometricians, however, and often provides sufficient accuracy. The MC is sophisticated and highly accurate; it can include almost any latent modeling variant, thereby allowing for excellent specificity, its only downside is its complexity. The current CFA in MC provided a marked savings in sample size.

PMH84

PERFORMANCE OF TWO INSTRUMENTAL VARIABLES TO EXAMINE THE RISK OF DEATH IN DUAL ELIGIBLE ELDERLY NURSING HOME RESIDENTS USING ANTIPSYCHOTIC AGENTS

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OBJECTIVES: To evaluate the performance of two instrument variables, namely physician and nursing home facility preference, to examine the risk of death in dual eligible elderly nursing home residents using antipsychotic agents. **METHODS:** A retrospective cohort design involving dual eligible nursing home residents 65 years and above was used. An instrumental variable analysis was conducted to evaluate the risk of mortality within 180 days of antipsychotic exposure. The physician's preference was operationalized based on the most recent antipsychotic prescription initiated by the physician. Nursing home facility preference was defined as the most frequently initiated antipsychotic agent in the nursing home. The performance of each instruments was evaluated based on the strength of association, covariate balance, and explanatory power in addition to endogeneity tests. The risk of death was modeled using extended Cox Proportional Hazard model based on two-stage residual inclusion method for instrumental variable analysis. **RESULTS:** Physician preference [Odd Ratio (OR) 3.97] and nursing home facility preference (OR 4.54) were strongly associated with antipsychotic use. The explanatory power in the multivariate models and covariate balance in the preference groups were similar with both instruments. Instrumental variable analysis involving physician preference, however, did not meet the criteria for endogeneity (Wu-Hausman $F = 1.49$, $P = 0.22$). Using nursing home facility preference as an instrument, the extended Cox model revealed that risk of death is greater among typical antipsychotic users in the initial 40 days [Hazard Ratio (HR) 2.76, 95% CI 2.11-3.62] but decreases after 40 days [HR 1.44, 95% CI 1.10-1.88] when compared to atypical users. **CONCLUSIONS:** Nursing home facility preference appears to be valid instrument in the nursing home population. Evaluation of instruments is critical in implementing instrumental variable analysis for pharmacoepidemiology research.

PMH85

A SCHIZOPHRENIA OR BIPOLAR TYPE I DISORDER REGISTRY: LESSONS LEARNED FROM CONDUCTING A REGISTRY STUDY WITH SAFETY NET PROVIDERS

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OBJECTIVES: Registries are increasingly used to collect information on effectiveness of new medications in real-world practice settings. Conducting a registry study focused on providers who treat vulnerable populations and have limited research experience can present unique challenges. The Research and Evaluation of Antipsychotic Treatment in Community Behavioral Health Organizations OUTcomes (REACH OUT) Registry is a naturalistic, longitudinal study of patients receiving primary treatment at community behavioral health organizations (CBHOs) to provide information on paliperidone palmitate, risperidone long-acting therapy, and other antipsychotics. This presentation discusses lessons learned thus far from the REACH OUT study. **METHODS:** REACH OUT recruits patients with schizophrenia or bipolar type I disorder from multiple CBHOs in the United States. Patients are identified by treating clinicians and screened by research coordinators to determine eligibility. A Web-based data collection tool is used to enter data obtained from patient self-reports, interviewer/clinician assessments, and medical records abstraction. Patients will be followed for 1 year with assessments at baseline, 6 months, and 12 months. **RESULTS:** Lessons learned thus far are 1) the value of collaborating with the provider member organization to recruit sites; 2) the need for buy-in from site management; 3) the importance of identifying dedicated staff committed to research endeavors; 4) the importance of selection of instruments that balance data collection burden and the desire for a variety of outcome measures; 5) benefits of vetting the draft protocol with potential sites to assess feasibility; and 6) the importance of working with sites to address individual needs (e.g., local internal review board approval). **CONCLUSIONS:** Registry studies focusing on patients treated by safety net providers, often with limited research experience, require unique considerations. Working closely with sites up-front and obtaining buy-in from site management and research staff have been crucial to REACH OUT thus far.

Neurological Disorders – Clinical Outcomes Studies

PND1

PRESCRIBING PATTERNS OF DRUGS HAVING ANTICHOLINERGIC ACTIVITY IN PATIENTS WITH ALZHEIMER'S DISEASE

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OBJECTIVES: Co-prescription of anticholinergic drugs with the traditional cholinesterase inhibitors treatment in patients suffering from Alzheimer's disease (AD) is not recommended. Yet the extent of anticholinergic drugs use is unknown. Conversely, the prescription of anticholinergic drugs is not contraindicated with the N-Methyl-D-Aspartic acid (NMDA) receptor antagonist. This study evaluates the pattern of usage of drugs with anticholinergic activity in geriatric patients with AD receiving cholinesterase inhibitors and NMDA receptor antagonist. **METHODS:** 654 patients suffering from AD above the age of 65 years were analyzed from NNHS 2004. The co-prescribed anticholinergic drugs were given a score of 0 to 3 using the Clinician-Rated Anticholinergic Drug Scale with values ranging from no, mild,